

OCT 21 2003

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**  
**Navitrack™ System – Total Hip Replacement CT-Free**

**Applicant:** ORTHOsoft Inc.  
75 Queen Street, suite 3300  
Montreal, Quebec  
Canada, H3C 2N6  
Tel.: 514 861 4074  
Fax: 514 866 2197

**Contact Person:** Christopher McLean

**Date Summary Prepared:** September 19, 2003

**Device Trade Name:** Navitrack™ System – Total Hip Replacement CT-Free

**Device Classification Name:** Stereotaxic Instrument (84 HAW); 21 CFR § 882.4560

**Predicate Device:**

Navitrack System™ – Total Hip Replacement CT-Free Cup, from Orthosoft Inc, 510(k) #K030827

**Device Description:**

Identically as in the predicate, the Navitrack™ System – Total Hip Replacement CT-Free device consists of a software-driven workstation, an optical tracking system, surgical instruments, and tracking accessories, designed to assist the surgeon in the placement of Total Hip Replacement (THR) components. Tracking devices are incorporated with given surgical instruments, as well as on to fixation bases that attach to the pelvis, such to allow the ability to track and display to the user their respective positions intra-operatively. The pelvis is displayed to the user in the form of its main alignment axes. The alignment axes are determined and recorded intra-operatively by identifying the key anatomical references that are used clinically to align and position the THR components. The instruments are schematically represented.

The modifications to the predicate are to additionally track the femur and femoral instrumentation similarly as is done for the pelvis, in order to also assist in the placement of the THR components for the femur.

**Indications for Use / Intended Use:**

The Navitrack™ System – Total Hip Replacement CT-Free is indicated for use as a stereotaxic instrument to assist in the positioning of hip replacement components.

It is a computer controlled image-guidance system equipped with a three-dimensional tracking sub-system. It is intended to assist in precisely positioning hip replacement components intra-operatively by displaying their positions relative to the joint's alignment axes as based on user-identified anatomical landmarks.

This is identical to the Navitrack System™ – Total Hip Replacement CT-Free Cup predicate.

**Technological Comparisons to the Predicate:**

The comparisons showed that the proposed device is substantially equivalent to the predicate, the Navitrack System – Total Hip Replacement CT-Free Cup. It is a modification to the predicate. The fundamental scientific technology of the Navitrack predicate is unchanged. It utilizes the same workstation and tracking technology. The modification consists in extending the capabilities of the predicate to also track the femur and its instrumentation in addition to the pelvis and its instrumentation in the predicate. Similarly as for the pelvis in the predicate, it employs the same method of having the user identify and digitize key landmarks from which the system determines femoral alignment axes relative to which the user can verify the placement of the femoral THR components. The software was correspondingly modified to handle the added capabilities, and the instrument set extended to include femoral instrumentation.

**Performance Data:**

Non-clinical tests were performed to assess that no new safety and efficacy issues were raised in the device. They consisted in verifying that the accuracy and performance of the system in depicting the positioning of the femoral THR component was adequate for its intended use.

**Conclusion:**

The information and data provided in this 510(k) Premarket Notification established that the Navitrack™ System – Total Hip Replacement CT-Free device is substantially equivalent to the Navitrack System™ – Total Hip Replacement CT-Free Cup predicate.



OCT 21 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Christopher McLean  
Regulatory Affairs and Quality Assurance Manager  
Orthosoft, Inc.  
75 Queen Street, Suite 3300  
Montreal, Quebec  
Canada, H3C 2N6

Re: K032917  
Trade/Device Name: Navitrack™ System – Total Hip Replacement CT-Free  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic instrument  
Regulatory Class: II  
Product Code: HAW  
Dated: September 19, 2003  
Received: September 22, 2003

Dear Mr. McLean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

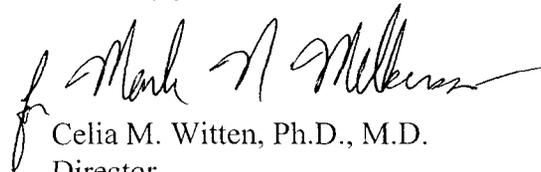
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Christopher McLean

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

